**United States Department of Agriculture** **Animal and Plant Health Inspection Service** **Washington, D.C. 20250**

# VETERINARY SERVICES (VS) NOTICE 98-09

**Subject:** Deregulation of Cell Culture Material For *In Vitro* Use

**Date:** October 30, 1998

**To:** Directors, VS Regions
Area Veterinarians in Charge, VS
Veterinary Medical Officers, VS

This Notice is to inform VS personnel and Plant Protection and Quarantine port inspectors of a new U.S. Department of Agriculture policy regarding the importation of certain cell cultures/lines and their products. The new policy replaces that contained in the version of VS Memorandum 593.1 dated November 9, 1989, which was canceled in March 1998. The memorandum is being replaced with a new version which reflects the recent deregulation of monoclonal antibodies for *in vitro* use and certain cell cultures/lines and their products for *in vitro* use.

Monoclonal antibodies (MAB) and cell culture materials were deregulated on the basis of risk analyses which concluded that the level of risk associated with importation of these products for *in vitro* use was acceptable (See VS Notice 98-03, March 9, 1998, for previous notification of the revised policy on MAB.) The conclusions of the risk analysis for MAB have been extended to include cell culture materials. However, since the risk analyses did not address cell culture material originating from livestock and avian species or for *in vivo* use, permits will continue to be required for these products.

Although it will no longer be necessary to obtain a permit, "U.S. Veterinary Permit for the Importation and Transport of Controlled Materials and Organisms and Vectors" (VS Form 16-6 and 16-6A) to import certain cell culture materials, products submitted for importation must be accompanied by written certification that the cell cultures/lines and their products are:

1. NOT of livestock or avian species origin;

2. Intended solely for *in vitro* use;

3. Produced in a facility that does not work with exotic disease agents affecting livestock or avian species; and

4. Do not produce antigens or contain genes of livestock or avian disease agents or do not produce monoclonal antibodies directed against livestock or avian disease agents.

Permits will continue to be required for cell cultures/lines and their products that are:

1. Intended for *in vivo* use;

2. Derived from livestock or avian species;

3. Originated from a laboratory which works with exotic disease agents affecting livestock and avian species; and

4. Produced antigens or contained genes of livestock or avian disease agents or are monoclonal antibodies directed against livestock or avian disease agents.

A major revision of the document, "Guidelines to Importation #1120," has been prepared. The revision, entitled, "Cell Cultures/Lines, Their Products, and Monoclonal Antibodies" has replaced the previous version, entitled, "Monoclonal Antibodies." Three other "Guidelines to Importation" have been revised to reflect the policy change. These are "#1101, Human and Non-Human Primate Material; "#1103, Live Laboratory Mammals," and "#1114, Recombinant Microbes, Cells, and Their Products." The new guidelines and application forms (VS 16-3 and 16-7) are available from the Animal Products Program through the automated document retrieval system at Area Code (301) 734-4952.

/s/

Thomas E. Walton
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Veterinary Services